Questions for the Panel

Questions relating to Effectiveness:

1. The sponsor proved their primary hypothesis of a 10% improvement in hemostasis (no need for additional agents during the procedure), but did not show an improvement in the secondary endpoints. Please discuss the clinical implications of the primary and secondary endpoint data.

2. The sponsor states in the submission that "Our clinical investigators believe that the routine use of BioGlue in these patients will allow them to modify their blood management protocol and should minimize the potentially life-threatening complication of postoperative hemorrhage." Please comment on whether there is adequate information to support the statement.

Question relating to Safety and Effectiveness

3. Based on the information provided in the premarket approval application, please discuss whether the information supports reasonable assurance of safety and effectiveness of the BioGlue.

Questions relating to safety and labeling:

One aspect of the pre-market evaluation of a new product is the review of its labeling. The labeling must indicate which patients are appropriate for treatment, identify potential adverse events with the use of the device, and explain how the product should be used to maximize benefits and minimize adverse effects. Please address the following questions regarding the product labeling:

4a. Please discuss the findings of the immunogenicity testing, especially as they relate to both physician and patient labeling issues. Should patients be advised of specific adverse events to be aware of that may suggest they are experiencing a sensitization reaction from the BioGlue?

4b. The sponsor conducted several animal studies to assess the potential for BioGlue to elicit an immune reaction. The information from these studies suggests that there may be a potential for sensitization to the bovine serum albumin (and related proteins) in the formulation. Information from the clinical studies is limited to assessing the product with short term follow-up. Sensitization reactions may occur longer-term. Please discuss whether sensitization has been adequately addressed with the clinical data as supplied. Are additional post-approval studies needed to assess the immune potential of BioGlue?

5. Please comment on the Indications for Use section as to whether it identifies the appropriate patient population for treatment with this device. The indications verbatim from the labeling currently read “BioGlue Surgical Adhesive is indicated for use as an adjunct to standard methods of cardiac and vascular repair such as sutures (or staples) to provide hemostasis.”

6. Please comment on the Directions for Use as to whether they adequately describe how the device should be used to maximize benefits and minimize adverse events.

7. Do you have any other recommendations regarding the labeling of this device?